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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,489	01/23/2001	Lisa Joanne Drewe	41577/252464	5644

23370 7590 01/22/2003

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EXAMINER	
SIEW, JEFFREY	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 01/22/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/744,489	Applicant(s) DREWE ET AL.	
	Examiner Jeffrey Siew	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6,8-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed 11/12/02 has been entered and fully considered. The pending claims to be examined are claims 1-6 & 8-16.

Drawings

2. The key in Figure 2 does not appear to follow the drawing or does not satisfactorily elucidate the drawing. Correction is required.

The response states that amended drawings will be timely submit drawings that address the objection. As such, the objection is maintained.

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Vary (WO 92/11390 9 July 1992).

Vary et al teach the use of a probe for detection nucleic acid sequence target by formation of triple helix which eliminates denaturation during detection (see **whole doc**. esp. abstract) . They teach detection of amplification of product duplexes. The triple helix forming duplex sequences may be endogenous to target sequence or they may be introduced by probes during PCR amplification by primers. The target sequence containing polypurine region (see page 5 lines 20 & 21) and the probe contains high polypyrimidine (see col. 4 line 25). They teach introducing polypyrimidine on 5' end of primer to introduce high polypurine target into amplified DNA (see page 30 line15-20). They teach detection on electrophoretic gel (see example 1).

The response is reminded that claim 13 is drawn to product and the intended use of the product that does not impart physical or functional may not bear patentable weight that distinguish it sufficiently from the prior art.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3-6,8 ,12 &14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vary (WO 92/11390 9 July 1992) in view of Ecker et al's(US5,641,625 June 24, 1997).

Vary et al teach the use of a probe for detection nucleic acid sequence target by formation of triple helix which eliminates denaturation during detection (see **whole doc**. esp. abstract) . They teach detection of amplification of product duplexes. The triple helix forming duplex sequences may be endogenous to target sequence or they may be introduced by probes during PCR amplification by primers. The target sequence containing polypurine region (see page 5 lines 20 & 21) and the probe contains high polypyrimidine (see col. 4 line 25). They teach introducing polypyrimidine on 5' end of primer to introduce high polypurine target into amplified DNA (see page 30 line15-20). They teach detection on electrophoretic gel (see example 1).

Vary et al do not teach peptide nucleic acid.

Ecker et al teach PNA probes which bind with high stability and specificity to double stranded DNA (see whole doc. esp. col. 4 line 4 line 47 & col. 15 line 1-5 & col. 4 line 35).

One of ordinary skill in the art would have been motivated to apply Ecker et al's PNA probes to Vary et al's detection method in order to provide a probe that binds specifically to

target sequence. It would have been prima facie obvious to apply Ecker et al's probe to specifically discriminate target sequence in Vary et al's amplification product.

Moreover, it would have been prima facie obvious to combine all the reagents i.e. Ecker et al's PNA probe and Vary et al's primers to perform the triple helix detection method into a single kit in order for the practitioner to perform the method efficiently.

5. The response filed 11/12/02 has been fully considered and deemed not persuasive. The response states that Vary et al does not teach a primer that introduces a polypurine rich region during amplification. Vary et al **do explicitly** teach a primer with a polypyrimidine rich region that introduces a polypurine rich region during amplification . Vary et al teach the use of SEQ ID NO: 4 or 5 or 6 as primers to amplify m. pt. Genomic DNA (see pages 16 & 17). The primers contain at 3' end M.pt. specific sequence and 5' end polypyrimidine rich (note the CT rich section) which introduces a polypurine rich region during amplification (see Figure 1). Moreover, the response states that the Vary et al and Ecker et al reference are not combinable because Ecker et al do not teach detection but rather drawn to method of modulating protein function. The basis of the 103 reference is the combination of the references. Vary et al teach the limitations of detection. Ecker et al teach the PNA advantageous properties of binding to double strand to form very stable triple helixes for binding to target. While Ecker et al do primarily teach protein modulation by binding PNA, they also **explicitly teach** the diagnostic and detection use of PNA compounds and binding to target (see col.4 lines 63 & **col.12 line 57- col.12 line 3**). Moreover, the critical point used in the 103 rejection is that Ecker et al teaches that PNA form exceptional stable triple helixes DNA binding ability. The fact that PNAs can be used in other

methods such as complex probe transcription modulation does not detract from one of ordinary skill in the art to apply his teachings to detection that employs PNAs advantageous binding aspect. Ecker et al teachings in fact very combinable to Vary et al's detection method because Ecker et al PNA teachings in other technologies which both involve the binding to target and polymerase inhibition would be very applicable to detection methods that involve only the binding to target. Ecker et al's teaching provide more than one of ordinary skill the motivation to combine with Vary et al's technique. Similarly the Frank Kamentskii prior art would be applicable to Vary et al because they teach that bis PNA may be used in PCR to avoid competing side reactions such as amplification of non target sequences in background and primer oligomerization. The teachings of additional uses of bis PNA do not detract from its beneficial properties that one of ordinary skill in the art would apply to Vary et al's detection method. As such the rejections over the 103 cited prior art are therefore maintained.

6. Claims 9-11, 15 & 16are rejected under 35 U.S.C. 103(a) as being unpatentable over Vary (WO 92/11390 9 July 1992) in view of Ecker et al's(US5,641,625 June 24, 1997) in further view of Wang et al (J. Am Chem . Soc. Vol. 118 pp. 7667-7670 1996).

The teachings and suggestions of Vary and Ecker et al are described previously.

Vary do not teach a biosensor.

Wang et al teach biosensor attached PNA probes for detection. (see whole doc. esp. abstract).

One of ordinary skill in the art would have been motivated to apply Wang et al biosensor PNA surface probes to the combined invention of Vary and Eckert et al detection method in

order to increase the high throughput and sensitivity of detection. Wang et al state that PNA biosensors provide faster hybridization and provided high sequence sensitivity without stringent control off hybridization conditions (see page 7670). It would have been prima facie obvious to apply Wang et al's biosensor to the Vary and Eckert et al's detection method in order to increase sequence sensitivity and high throughput analysis.

7. Claims 1-6,8, 13 & 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vary (WO 92/11390 9 July 1992) in view of Frank-Kamenetskii et al (WO97/14793 24 April 1997)

Vary et al teach the use of a probe for detection nucleic acid sequence target by formation of triple helix which eliminates denaturation during detection (see whole doc. esp. abstract) . They teach detection of amplification of product duplexes. The triple helix forming duplex sequences may be endogenous to target sequence or they may be introduced by probes during PCR amplification by primers. The target sequence containing polypurine region (see page 5 lines 20 & 21) and the probe contains high polypyrimidine (see col. 4 line 25). They teach introducing polypyrimidine on 5' end of primer to introduce high polypurine target into amplified DNA (see page 30 line15-20).

Vary et al do not teach bis-peptide.

Frank-Kamenetskii et al teach a bis-PNA fro binding to double stranded DNA (see whole doc. esp. abstract). They teach that PNA clamps show high stability and may be used in PCR to avoid competing side reactions such as amplification of non target sequences in background and primer oligomerization.

One of ordinary skill in the art would have been motivated to apply Frank Kamenetskii et al's PNA probes to Vary et al's detection method in order to provide a probe that binds specifically to target sequence. It would have been prima facie obvious to apply Ecker et al's probe to enhance detection target sequence in Vary et al's amplification product.

SUMMARY

8. No claims allowed.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CONCLUSION

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

JEFFREY SIEW
PRIMARY EXAMINER

January 22, 2003